

REC'D 01 JUL 2004

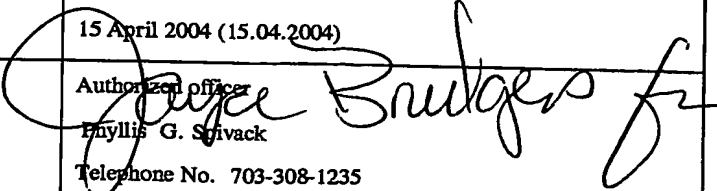
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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference SYNER 1 WO		FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US03/24691	International filing date (day/month/year) 08 August 2003 (08.08.2003)	Priority date (day/month/year) 00 August 2002 (02.08.2002)	
International Patent Classification (IPC) or national classification and IPC IPC(7): A61K 31/198 and US Cl.: 514/567			
Applicant SYNERGIA PHARMA, INC.			
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>3</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of <u> </u> sheets.</p> <p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of report with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>			
Date of submission of the demand 02 March 2004 (02.03.2004)		Date of completion of this report 15 April 2004 (15.04.2004)	
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230		Authorized officer  Phyllis G. Schwack Telephone No. 703-308-1235	

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US03/24691

I. Basis of the report

1. With regard to the elements of the international application:*

- ☒ the international application as originally filed.
- ☒ the description:
 pages 1-9 _____ as originally filed
 pages NONE _____, filed with the demand
 pages NONE _____, filed with the letter of _____.
- ☒ the claims:
 pages 10-12 _____, as originally filed
 pages NONE _____, as amended (together with any statement) under Article 19
 pages NONE _____, filed with the demand
 pages NONE _____, filed with the letter of _____.
- ☒ the drawings:
 pages NONE _____, as originally filed
 pages NONE _____, filed with the demand
 pages NONE _____, filed with the letter of _____.
- ☐ the sequence listing part of the description:
 pages NONE _____, as originally filed
 pages NONE _____, filed with the demand
 pages NONE _____, filed with the letter of _____.

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/fig NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US03/24691

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims <u>NONE</u>	YES
	Claims <u>1-33</u>	NO
Inventive Step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-33</u>	NO
Industrial Applicability (IA)	Claims <u>1-33</u>	YES
	Claims <u>NONE</u>	NO

2. CITATIONS AND EXPLANATIONS

Claims 1-33 fail to meet the criteria of PCT Articles 33(2) and 33(3) as Takagi teaches preventing headaches comprising administering threo-3-(3, 4-dihydroxyphenyl)serine, a norepinephrine precursor. Further, the claims lack an inventive step. See the abstract. A treatment of headache would reasonably encompass all types of headache. Takagi is silent with respect to a patient population suffering from Parkinson's disease.

Claims 1-33 meet the criteria of PCT article 33(4) as they are directed to preventing headache.

PATENT COOPERATION TREATY

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NOTE OF INFORMAL COMMUNICATION WITH THE APPLICANT

(PCT Rule 66.6)

International application No. PCT/US03/24691	Applicant's or agent's file reference SYNER 1 WO	Date of informal communication (day/month/year) 15/04/04
Applicant SYNERGIA PHARMA, INC.		

<u>Communication</u> <input checked="" type="checkbox"/> by telephone <input type="checkbox"/> personal	<u>Participants</u> <input checked="" type="checkbox"/> Applicant: SYNERGIA PHARMA, INC. <input checked="" type="checkbox"/> Agent: Richard M. Lebovits <input checked="" type="checkbox"/> Examiner(s): Phyllis G. Spivack	<input checked="" type="checkbox"/> Identity checked <input type="checkbox"/> authorization checked <input type="checkbox"/> personally known
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Summary of communication:

Mr. Lebovits agreed to the execution of the International Preliminary Examining Report (409) to advance prosecution.

- ☐ ~~An extension of time limit is granted (Form PCT/IPEA/427).~~
- ☒ A copy of this note is being sent to the applicant with Form PCT/IPEA/429.

PCT/IPEA/424.

Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	<div style="text-align: center;"> </div> Authorized officer Phyllis G. Spivack Telephone No. 703-308-1235
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Form PCT/IPEA/428 (July 1992)